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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,584	10/11/2005	Shyam S Mohapatra	USF-183XC1	4246

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
01/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,584	MOHAPATRA, SHYAM S	
	Examiner	Art Unit	
	Q. JANICE LI, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,20,21,23-25,27-30,43 and 48-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,20,21,23-25,27-30,43,52-60 and 62* is/are rejected.

7)☐ Claim(s) *48-51 and 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/08 has been entered.

The amendment and remarks filed on 10/14/08 are acknowledged. Claims 13, 20, 23, 25, 28-30, 52 have been amended, claims 15, 44, 46, 47 have been canceled. Claims 59-62 are newly submitted.

Election/Restrictions

Applicant's election with traverse of Group III, and species election drawn to **SEQ ID No: 5** in the response filed 6/13/07 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted the claim 13 as originally filed embraces a genus of nucleic acids encoding numerous NHP peptides, each has distinct structure and functional characteristics, and each possesses separate status in the art, hence qualified as independent and distinct inventions. In view of the restriction requirement issued 5/15/07, and the prosecution history so far, claims drawn to a nucleic acid encoding a

peptide comprising SEQ ID No: 6 is hereby rejoined and will be examined in this application, but not nucleic acids encoding additional NHP peptides.

To this end, it is noted due to the amendment of the sequence listing, SEQ ID Nos: 12 & 13 are no longer directed a nucleic acid encoding either instant SEQ ID No: 5 or 6, and hence are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 13, 20, 21, 23-25, 27-30, 43, 45, 48-62 are under current examination.

Specification

The specification is objected to because the listing for SEQ ID No: 5 does not match the description of the specification. The amendment of the specification submitted 1/10/2008 states, “SEQ ID No: 5 is the amino acid sequence of cloned mouse pNHP73-102. However, the 29 amino acid residues only account for NHP 73 through 101, if it starts from "gly” at position 73.

Appropriate clarification is required.

Claim Objection

Claims 52-58, 62 are objected to because they contain subject matter drawn to non-elected inventions (SEQ ID Nos: 12, 13). Upon election of an invention for prosecution, the claim should be amended so that it only reads on the elected invention. Appropriate correction is required.

Claims 48-51, 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/319,529, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the provisional application fails to disclose SEQ ID No: 5 or 6. Thus, the priority date for the elected species, SEQ ID Nos: 5 & 6 has been established as the filing date of the PCT application, i.e. 9/8/03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 20, 23, 25, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by *Seidman et al* (Science 1984;226:1206-9, IDS).

Claims embrace homologs of SEQ ID No: 5. The specification teaches that the NHP homologs include peptides containing all or *part* of an exemplified NHP polypeptide sequence, including *conservative substitutions* (Specification, paragraph 0049).

Seidman et al teach an expression vector comprising a nucleic acid sequence encoding a natriuretic peptide hormone NHP, which comprising part of the instant SEQ ID No: 5, and host cells comprising the vector were used at least for propagating the vector. Accordingly, *Seidmen et al* anticipate instant claims.

Claims 13, 20, 21, 23-25, 28-30, 43, 45, 59, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by *Shimkets* (US 6,013,630).

Shimkets teaches a pharmaceutical composition comprising a nucleic acid sequence encoding an artrial natriuretic factor (ANF), while the preferred embodiment is a 28-amino acid peptide (SEQ ID No: 1) of the rat or human ANF, which comprises residue 3 through 29 of the instant SEQ ID No: 5, a homolog of instant SEQ ID No: 5.

Shimkets also teaches a nucleic acid encoding a ANF comprising instant SEQ ID No: 6 (SEQ ID No: 2 of *Shimkets*). *Shimkets* goes on to teach plasmid vectors and host cells comprising the nucleic acid (§ 5.2). *Shimkets* also teaches vectors could be used in gene therapy as a therapeutic agent in a pharmaceutical carrier such as encapsulated in liposomes (§ 5.3.2). Accordingly, *Shimkets* anticipates instant claims.

Claims 20, 21, 23-25, 59 are rejected under 35 U.S.C. 102(b) as being anticipated by *Zivin et al.* (PNAS 1984;81:6325-9, IDS).

Claims are directed to nucleic acids, vectors, host cells comprising nucleic acid encoding a NHP comprising SEQ ID No: 6 and its homologs.

Zivin teaches a nucleic acid sequence encoding a natriuretic hormone peptide (NHP) comprising amino acid residues of instant SEQ ID No: 6 (see figure 1), plasmid vectors comprising the nucleic acids (pBR322), and host cells comprising the vector. Accordingly, *Zivin* anticipates instant claims.

Claims 20, 21, 23-25, 53-55, 59, 62 are rejected under 35 U.S.C. 102(a) as being anticipated by *Collins et al.* (PNAS 2002;99;16899-16903).

Claims are directed to a nucleic acid comprising the nucleotide sequence SEQ ID No: 19, which is also a nucleic acid encoding a peptide comprising SEQ ID No: 6.

Collins discloses a nucleic acid sequence comprising instant SEQ ID No: 19. Vectors and host cells have been used in cloning and sequencing. Accordingly, *Collins* anticipates instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Shimkets* (US 6,013,630), in view of *Nicolaas et al* (Pharm Res 1996;13:1686-92).

Shimkets teach a pharmaceutical composition comprising a nucleic acid sequence encoding a natriuretic hormone peptide (SEQ ID No: 1), which is a homolog of instant SEQ ID No: 5. *Shimkets* does not teach the composition further comprises a chitosan.

Nicolaas remedy the deficiency by establishing it was well known in the art before instant priority date that chitosans could enhance small peptide drug delivery (e.g. the abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Shimkets* by simply including chitosan for NHP peptide delivery as taught by *Nicolaas* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because of enhanced delivery efficiency. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI, M.D.** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI/
Primary Examiner,
Art Unit 1633

QJL
January 10, 2009